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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/804,014	03/12/2001	Li Li	15966-721	8877

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EXAMINER	
SULLIVAN, DANIEL M	
ART UNIT	**PAPER NUMBER**
1636	14

DATE MAILED: 09/20/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/804,014	LI ET AL.	
	Examiner	Art Unit	
	daniel Sullivan	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-43 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-43 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I-VIII. Claim1, 2, 3, 4, 29 and 32, drawn to an isolated polypeptide, wherein each of Groups I-VIII are distinguished in that they are drawn to the patentably distinct amino acid sequences, or variants of the sequences, set forth as SEQ ID NO:2, 4 and 6; 8; 10; 12 and 14; 16; 18; 20; or 22, classified in class 530, subclass 350.

IX-XVI. Claims 5-14, 30 and 33, drawn to an isolated nucleic acid molecule, wherein each of Groups IX-XVI are distinguished in that they are drawn to a nucleic acid comprising a nucleic acid encoding the patentably distinct amino acid sequences set forth as SEQ ID NO:2, 4 and 6; 8; 10; 12 and 14; 16; 18; 20; or 22, classified in class 536, subclass 23.5.

XVII-XXIV. Claims 15-17, 31 and 34, drawn to an antibody, wherein each of Groups XVII-XXIV are distinguished in that they are drawn to antibodies that bind the patentably distinct amino acid sequences, or variants of the sequences, set forth as SEQ ID NO:2, 4 and 6; 8; 10; 12 and 14; 16; 18; 20; or 22, classified in class 530, subclass 387.9.

XXV-XXXII. Claims 18 and 40, drawn to a method of determining the presence or amount of a polypeptide comprising introducing an antibody that binds immunospecifically, wherein each of Groups XXV-XXXII are distinguished in that they are drawn to antibodies that bind the patentably distinct amino acid

sequences, or variants of the sequences, set forth as SEQ ID NO:2, 4 and 6; 8; 10; 12 and 14; 16; 18; 20; or 22, classified in class 435, subclass 7.1.

XXXIII-XL. Claims 19 and 41, drawn to a method of determining the amount or presence of a nucleic acid molecule comprising introducing a probe that binds to the nucleic acid molecule, wherein each of Groups XXXIII-XL are distinguished in that they are drawn to probes that encode the patentably distinct amino acid sequences, or variants of the sequences, set forth as SEQ ID NO:2, 4 and 6; 8; 10; 12 and 14; 16; 18; 20; or 22, classified in class 435, subclass 6.

XLI-XLVIII. Claim 20, drawn to a method of identifying an agent that binds to a polypeptide comprising introducing said polypeptide, wherein each of Groups XLI-XLVIII are distinguished in that they are drawn the patentably distinct polypeptides, or variants of the polypeptides, set forth as SEQ ID NO:2, 4 and 6; 8; 10; 12 and 14; 16; 18; 20; or 22, classified in class 435, subclass 4.

XLIX-LVI. Claims 21, 22 and 36-38, drawn to a method for identifying a potential therapeutic or screening for a modulator comprising providing a cell or animal expressing a polypeptide, wherein each of Groups XLIX-LVI are distinguished in that they are drawn the patentably distinct polypeptides, or variants of the polypeptides, set forth as SEQ ID NO:2, 4 and 6; 8; 10; 12 and 14; 16; 18; 20; or 22, classified in class 435, subclass 4.

LVII-LXIV. Claim 23, 24 and 43, drawn to a method of treating or preventing a pathology associated with a polypeptide, wherein each of Groups LVII-LXIV are distinguished in that they are drawn the patentably distinct polypeptides, or

variants of the polypeptides, set forth as SEQ ID NO:2, 4 and 6; 8; 10; 12 and 14; 16; 18; 20; or 22, classified in class 530, subclass 350.

LXV-LXXII. Claims 25 and 26, drawn to a method of treating or preventing a pathology comprising administering a NOVX nucleic acid, wherein each of Groups LXV-LXXII are distinguished in that they are drawn to a nucleic acid comprising a nucleic acid encoding the patentably distinct amino acid sequences set forth as SEQ ID NO:2, 4 and 6; 8; 10; 12 and 14; 16; 18; 20; or 22, classified in class 514, subclass 44.

LXXIII-LXXX. Claims 27 and 28, drawn to a method of treating or preventing a pathology comprisng administering a NOVX antibody, wherein each of Groups LXXIII-LXXX are distinguished in that they are drawn to antibodies that bind the patentably distinct amino acid sequences, or variants of the sequences, set forth as SEQ ID NO:2, 4 and 6; 8; 10; 12 and 14; 16; 18; 20; or 22, classified in class 530, subclass 387.9.

LXXXI-LXXXVIII. Claim 42, drawn to a method of treating a pathological state comprising administering a polypeptide, wherein each of Groups LXXXI-LXXXVIII are distinguished in that they are drawn to the patentably distinct amino acid sequences, or variants of the sequences, set forth as SEQ ID NO:2, 4 and 6; 8; 10; 12 and 14; 16; 18; 20; or 22, classified in class 530, subclass 350.

The inventions are distinct, each from the other because of the following reasons:

The inventions are first restricted based on their being drawn to structurally different, and therefore patentably distinct, amino acid sequences. The sequences are separated as SEQ ID

NO:2, 4 and 6 (Groups I, IX, XVII, XXV, XXXIII, XLI, XLIX, LVII, LXV, LXXIII and LXXXI), 8 (Groups II, X, XVIII, XXVI, XXXIV, XLII, XLX, LVIII, LXVI, LXXIV and LXXXII), 10 (Groups III, XI, XIX, XXVII, XXXV, XLIII, XLXI, LIX, LXVII, LXXV and LXXXIII), 12 and 14 (Groups IV, XII, XX, XXVIII, XXXVI, XLIV, XLXII, LX, LXVIII, LXXVI and LXXXIV), 16 (Groups V, XIII, XXI, XXIX, XXXVII, XLV, XLXIII, LXI, LXIX, LXXVII and LXXXV), 18 (Groups VI, XIV, XXII, XXX, XXXVIII, XLVI, XLXIV, LXII, LXX, LXXVIII and LXXXVI), 20 (Groups VII, XV, XXIII, XXXI, XXXIX, XLVII, XLXV, LXIII, LXXI, LXXIX and LXXXVII) and 22 (Groups VIII, XVI, XXIV, XXXII, XL, XLVIII, XLXVI, LXIV, LXXII, LXXX and LXXXVIII).

Because these inventions are distinct for the reasons given above and the search required for each Group is unique, restriction for examination purposes as indicated is proper.

The nucleic acids of Inventions IX-XVI are related to the protein of Inventions I-VIII by virtue of encoding the same. The DNA molecule has utility for the recombinant production of the protein in host cells. Although the DNA molecule and protein are related since the DNA encodes the specifically claimed protein, they are distinct inventions because they are physically and functionally distinct chemical entities, and the protein product can be made by another and materially different process, such as by synthetic peptide synthesis or purification from the natural source. Further, the DNA may be used for processes other than the production of the protein, such as nucleic acid hybridization assay.

The polypeptides of Inventions I-VIII are related to the antibodies of Inventions XVII-XXIV by virtue of binding affinity. Although the polypeptides and antibodies are related since the antibody binds to the polypeptide and can be raised by immunization with the polypeptide,

they are distinct inventions because they are physically and functionally distinct chemical entities, and the antibody can be made obtained by another and materially different process, such as by purification from a natural source or by immunization with chemically synthesized peptides. Further, the polypeptide may be used for processes other than the production of the antibody, such as a standard in an assay for the presence of the protein.

The nucleic acids of Inventions IX-XVI are related to the antibodies of Invention XVII-XXIV by virtue of the antibodies' binding affinity for a protein encoded by the nucleic acid. Although the nucleic acids and antibodies are related via the polypeptide encoded by the nucleic acids, which binds to the antibodies and can be used to make the antibodies by immunization, they are distinct inventions because they are physically and functionally distinct chemical entities, and the antibody can be made obtained by another and materially different process, such as by purification from a natural source or by immunization with chemically synthesized peptides. Further, the nucleic acid may be used for processes other than the production of the protein, such as a nucleic acid hybridization assay.

Inventions I-VIII are related to Inventions XLI-XLVIII and LXXXI-LXXXVIIII as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polypeptide can be used in each of the materially different processes of inventions XLI-XLVIII and LXXXI-LXXXVIIII.

Inventions IX-XVI are related to inventions XXXIII-XL, XLI-XLVIII, LXIX-LVI and LXV-LXXII, and Inventions XVII-XXIV are related to Inventions XXV-XXXII, LVII-LXIV and LXXIII-LXXX as product and process of use. Again, in each case the products can be used in the materially different processes to which the method Groups are drawn.

Each of the methods, Groups XXV-XXXII, XXXIII-XL, XLI-XLVIII, XLIX-LVI, LVII-LXIV, LXV-LXXII, LXXIII-LXXX and LXXXI-LXXXVIII are distinct. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as capable of use together and have different modes of operation as evidenced by their use of patentably distinct products.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel M Sullivan whose telephone number is 703-305-4448. The examiner can normally be reached on Monday through Friday 8-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel can be reached on 703-305-1998. The fax phone numbers for the organization where this application or proceeding is assigned are 703-746-9105 for regular communications and 703-746-9105 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

dms
September 16, 2002

JAMES KETTER
PRIMARY EXAMINER